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| 08/944,234      | 10/06/1997  | VINCENT BRYAN        | A8038               | 1173             |

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EXAMINER

NGO, LIEN M

|          |              |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

3727

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

08/944,234

Applicant(s)

KUNZLER ET AL.

Examiner

LIEN TM NGO

Art Unit

3727

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 4 and 8-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-7, 13-28, 30-35, 37-50, 52-57, 59-61, 67-71, 73-76, 78-85, 87-92, 94-97, 100-102, 104-109, 111, 114-125, 128, 130-138 is/are rejected.
- 7) ☒ Claim(s) 126, 127 and 129 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**Continuation of Disposition of Claims: Claims pending in the application are 1-28, 30-35, 37-50, 52-57, 59-61, 67-71, 73-76, 78-85, 87-92, 94-97, 100-102, 104-109, 111 and 114 -138 .**

## **DETAILED ACTION**

### ***Specification***

1. The amendment filed 12/4/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The original disclosure does not support the method of milling a vertebral body using the present invention drill head in paragraph [52], for example, "with a form cutter having at least one milling surface selected a predetermined surface contour in on of the adjacent vertebral bodies as the form cutter is moved by drive means 24". Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 131, 134 and 137 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. For example:

In claim 131, it cannot be understood why a form cutter having a convex shape can prepare the bone to accept a concave-convex shape of an endoprosthesis.

In claim 134, "said form cutter has at least one vertebral body surface contour milling surface" is not supported in the specification.

In claim 137, "said surface contour being generally parallel to said elongated shaft portion" is not supported in the specification".

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 130, 135 and 133 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 130 and 135, "the head can perform milling action" and "the direction of head entry" are lack antecedent basis.

In claim 133, it cannot be determined what is "means for preparing a space".

The limitation of "a form cutter mountable on said housing and movable by said drive means" can be considered of "means for preparing a space"

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 5-7, 13-28, 30-35, 37-50, 52-57, 59-61, 67-71, 73-76, 78-85, 87-92, 94-97, 100-102, 104-109, 111, 114 –125, 128, 130-138 are rejected under 35 U.S.C. 102(b) as being anticipated by Scheicher (4,197,645).

In regard to claims 1-3, 5-7, and 13-24, Scheicher discloses, in figs.1-4 and 13-18, a milling apparatus or a device for preparing a space in human bone to receive an implant, which also is capable of preparing a space in a human spine to receive an insert if one desires to do so. Said milling apparatus comprises a drill head 11, a rotary form cutter 5, a drive means 40, elongate housing 3, said form cutter has a convex shape, a groove, and provided with a beveled gearing surface 37, the height of profile of the form cutter is approximately 9 mm (2.5 – 10 mm), as disclosed in col.17, line 56, said drive means having a pinion gear 39, and said cutter having a support shaft 8 which forms an angle approximately 96 degrees to the drive means 40, (angle approximately 96 degrees which generally could be 90 degrees).

The statement of intended use of the device for preparing a space in a human spine to receive and insert between adjacent vertebral bodies has been carefully considered, but is deemed not to impose any structural limitations on the claims patentably distinguishable over the Scheicher which is capable of being used as claimed if one desires to do so, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate

the claimed article from the prior art article satisfying the claimed structural limitations.  
Ex parte Masham, 2 USPQ2d 1647 (1987).

In regard to claims 25-28, 30-35, 37-50, 52-57, 59-61, 67-71, 73-76, 78-85, 87-92, 94-97, 100-102, 104-109, 111, 114 –125, 128, 130-138, Scheicher device disclose all limitations substantially as claimed, such as, the form cutter has at least one milling surface 5a, 5b, 5c (see figs. 1-3) that is capable to create a contour in one of the adjacent vertebral bodies; the gear 39 of the drive means is configured to mate with corresponding teeth 39 on the cutter (see figs. 5b, 13 and 14).

***Allowable Subject Matter***

8. Claims 126, 127 and 129 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

9. Applicant's arguments filed 1/25/05 have been fully considered but they are not persuasive.

In response to applicant's argument of claim 1, Scheicher discloses a form cutter is capable of imparting a shape to the bone of vertebral bodies which mates with the predetermined surface shape ... wherein the profile of the form cutter is of a height capable of being admitted into the space between two opposing vertebral bodies.

Examiner notes that the height of profile of the form cutter is approximately 9 mm (2.5 –

10 mm), as disclosed in col.17, line 56; therefore, the form cutter is capable of being admitted into the space between two opposing vertebral bodies. And Scheicher teaches, in col. 1, lines 5-12, the invention concerns a drill head or a bone drill or milling cutter for preparing bone cavities into which a prosthesis elements can be inserted; therefore, the Scheicher drill head is capable for preparing the bone of two opposing vertebral bodies to accept an endoprosthesis device". Examiner notes further that the shape or structure of the prosthesis device is not required in the claim.

In response to applicant's argument of claim 15, the claim requires the angle of between the support shaft of form cutter and the drive shaft is "approximate 96 degrees" but not exactly 96 degrees; therefore, examiner may consider the angle between the support shaft 8a of form cutter and the drive shaft 40 (see fig. 5a) in the Scheicher as approximate 96 degrees

In response to applicant's argument of claims 18, 25, 41, 47, 49, 67, 82, 97, 114, 120, 121, 132 the statement of intended use of a device for preparing a space in a human spine to accept a predetermined shape of an endoprosthesis between adjacent vertebral bodies has been carefully considered, but is deemed not to impose any structural limitations on the claims patentably distinguishable over the Scheicher which is capable of being used as claimed if one desires to do so, since it has been held that a recitation with respect to the manner in which a claimed article is intended to be employed does not differentiate the claimed article from the prior art article satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).



In response to applicant's argument of claim 128, Scheicher discloses, in fig. 3, the form cutter having at least on milling surface selected to create a concaval-convex surface contour in a bone body or capable of creating a concaval-convex surface contour in on of the adjacent vertebral bodies.

In response to applicant's argument of claim 130, Scheicher discloses, in fig. 34, a single form cutter.

In response to applicant's argument of claims 131, 135, Scheicher discloses, in fig. 2, a form cutter having a convex-shape and a head that can perform milling action (rotation) in a direction angled away form the direction of head entry into a space of a bone body.

In response to applicant's argument of claims 133, claim 133 is not considered to invoke means plus function under 112, six paragraph because the means for preparing a space includes "form cutter mountable on said housing and movable by said drive means" would be considered as a sufficient structure modified the means for achieving the function of preparing a space.

The phrase "mean for" must not be modified by sufficient structure, material or acts for achieve the specified function (see MPEP 2181).

The drill head of Scheicher can be considered a means that is capable of preparing a space in a human spine as claimed.

In response to applicant's argument of claim 134, the drill head of Scheicher is capable of creating a surface contour in one of adjacent vertebral bodies; therefore, the contour

milling surface of the form cutter (for example in fig. 2) can be considered as a vertebral body surface contour milling surface when one desires to do it in the vertebral bodies.

In response to applicant's argument of claim 136, the milling surface of Scheicher is positioned (in fig. 1) to mill or rotation in a direction perpendicular to the elongated shaft portion 3.

In response to applicant's argument of claim 137, Scheicher discloses, in fig. 3, an elongated shaft portion 8c, and a form cutter 5 having at least on milling surface selected to create a surface contour being parallel to the elongated shaft portion.

In response to applicant's argument of claim 138, Scheicher discloses, in figs. 60-63, form cutter having milling surfaces (short surface) being capable to be entirely within an area formed by the adjacent vertebral bodies during milling.

### ***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LIEN TM NGO whose telephone number is 571-272-4545. The examiner can normally be reached on Monday through Friday from 8:30 AM -6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LEE YOUNG can be reached on 571-272-4549. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LIEN TM NGO  
Primary Examiner  
Art Unit 3727

March 29, 2005



LIEN M. NGO  
PRIMARY EXAMINER